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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,188	09/21/2000	Scott E. Andersen	38-21(51464)B	8378

7590 01/29/2003

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EXAMINER	
GUNTER, DAVID R	
ART UNIT	PAPER NUMBER
1634	11

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/667,188	ANDERSEN ET AL.	
	Examiner	Art Unit	
	David R. Gunter	1634	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2, and 11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. This action is in response to Amendment B, paper number 10, received November 11, 2002. The amendment has been fully considered and entered. The previous rejections in the office action dated August 1, 2002 (paper number 9) under 35 U.S.C. 101 and 112 are maintained. All of the arguments have been thoroughly considered and are discussed below. The examiner acknowledges the cancellation of claims 3-10 and the addition of claims 11-15. Claims 1, 2, and 11-15 are under prosecution.

Maintained Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 2, and newly added claims 11-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any polynucleotide. Note that this rejection is newly applied to claims 11-15. The specification discloses many potential uses for the polynucleotide including identifying promoters involved in gene regulation (page 38, lines 4-6), determining whether a plant contains a mutation (page 38, lines 19-20), and acting as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function

(page 15, lines 20-24). These are non-specific uses that are applicable to polynucleotides in general and not particular or specific to the polynucleotide claimed

Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polynucleotides such that another non-asserted utility would be well established for the compounds.

3. Claims 1 and 2, and newly added claims 11-15 are also rejected under 35 U.S.C. 112, first paragraph. Note that this rejection is newly applied to claims 11-15. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well

established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

4. The applicant's arguments have been fully considered and have not been found persuasive.

5. The current USPTO utility guidelines state [emphasis added]:

> "Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the specific and substantial tests (see below).
>
> "Specific Utility" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.
>
> "Substantial utility" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying

compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. ' 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility."

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial asserted utility would be considered to be met.

A "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

6. In the last paragraph of page 3 and the first paragraph of page 4 the applicant traverses the examiner's assertion that the claimed invention is not supported by either a specific or substantial utility. The applicant asserts that "*the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence of polymorphisms, isolating specific promoter sequences, and to obtain nucleic acid homologues, etc.*" (page 4, first paragraph).

The utilities asserted for the invention in the specification and re-iterated in the applicant's arguments are not specific because they are applicable to nucleic acids in general and not only to the claimed invention in particular. The utility guidelines state that a specific utility must be "specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a 'gene probe' or 'chromosome marker' would not be considered to be specific in the absence of a disclosure of a specific DNA target." Any nucleic acid molecule from any source can be used to determine the presence of polymorphisms, isolate specific promoter sequences, and obtain nucleic acid homologues, and therefore the asserted utilities are non-specific. The asserted non-specific utilities do not take advantage of the specific properties of the nucleic acid sequence of SEQ ID NO: 1.

In addition, the asserted utilities for the nucleic acid of SEQ ID NO:1 are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a

specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving the claimed nucleic acid have asserted or identified specific, substantial, or well-established utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility.

7. In paragraph 2 of page 4, the applicant seeks to make an analogy between the nucleic acid of the current invention and a microscope, stating that "*[m]any of the presently disclosed utilities are analogous to the utilities of a microscope, i.e., the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope.*"

The nucleic acid of the present invention is not analogous to a microscope. A microscope has a specific, credible, and substantial utility of magnifying images to allow the visualization of items too small to be seen by the unaided eye. This utility is specific for a microscope and is based on the physical structure of the lenses and mirrors present within the microscope. Other similar devices such as telescopes or periscopes also contain combinations of lenses and mirrors, but it is the specific structure of the microscope, the specific arrangement of lenses and mirrors, that gives a microscope its utility.

The asserted non-specific utilities for the nucleic acid of SEQ ID NO: 1 do not take advantage of the specific properties of nucleic acid sequence of SEQ ID NO: 1. Any nucleic acid molecule from any source can be used for a plurality of processes such as determining the presence of polymorphisms, isolating specific promoter sequences, or obtaining nucleic acid

homologues, and therefore the asserted utilities are non-specific. The utility guidelines state that a specific utility must be "specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a 'gene probe' or 'chromosome marker' would not be considered to be specific in the absence of a disclosure of a specific DNA target."

8. In the third paragraph of page 4, the applicant asserts "*the examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather, the examiner attempts to undermine the existing utilities by stating that these are 'non-specific uses that are applicable to polynucleotides in general.'*" Beginning in the last paragraph of page 5 through the middle of page 6 the applicant states "*the examiner states that the credibility of the presently asserted utilities has not been assessed. ... The examiner 'has the initial burden of challenging a presumptively correct assertion of utility.... The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion.'* The applicant concludes with the assertion "*Here, the examiner has not even attempted to meet this burden. Thus, the examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.*"

The examiner agrees that no evidence was presented to challenge the credibility of the disclosed utilities. The examiner does not question the credibility of the disclosed utility for the claimed polynucleotide. However, the finding that a utility is credible does not necessarily indicate that the utility is also specific and substantial. The utility guidelines state "nucleic acids

could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the specific and substantial tests." The examiner maintains that the disclosed utilities for the present invention are credible, but are also non-specific and not substantial. The asserted utilities do not take advantage of the specific structure, sequence, or properties of the claimed SEQ ID NO:, but rather are uses common to all polynucleotides. The utility of an invention must satisfy three criteria in order to be valid: the utility must be credible, specific, and substantial. The assertion that the utility of the present invention is credible does not in any way affect the fact that the utility is also non-specific and not substantial.

9. In the fourth paragraph of page 4 and the first paragraph of page 5 the applicant asserts "*the examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose*." The applicant then seeks to make an analogy between the polynucleotide of the present invention and a golf club. The applicant states "*such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, i.e., hitting golf balls.... Thus it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.*"

A golf club is not structurally or functionally analogous to the nucleic acid of the present invention. A golf club has a specific, substantial, and credible utility: to hit a golf ball in an effective and controlled manner. This utility is considered a real-world context of use, and is immediately apparent with no further experimentation needed to determine its use. This utility is

directly dependent upon the structure of the golf club and the materials of which it is composed. The asserted utilities for the nucleic acid of the present invention are not dependent on the structure (sequence) of the nucleic acid. The unique combination of the nucleotides within a nucleic acid molecule determines its specific function or activities. The asserted utilities for the present invention do not take advantage of the particular combination of nucleic acids in the present invention but rather rely on properties common to all nucleic acids. The utility is therefore considered non-specific.

10. The rejection of the claim 1, 2 and 11-15 under 35 U.S.C. 101 is maintained for the reasons set forth above. Note that this rejection is newly applied to claims 11-15.

New Grounds for Rejection - 35 USC § 112, Necessitated by Amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13-15 recite substantially purified nucleic acid molecules having between 95% and 100% sequence identity to SEQ NO: 1 or a complement thereof (claim 13), a substantially purified nucleic acid having between 99% and 100% sequence

identity with SEQ ID NO: 1 (claim 14), and a substantially purified nucleic acid according to claim 13 wherein the nucleic acid comprises a region having a single nucleotide polymorphism. These claims read on a very broad genus of nucleic acid molecules which includes variants, homologs, and mutants of SEQ ID NO: 1, with either retained or altered function.

Beyond providing the sequence data for SEQ ID NO: 1, however, the specification provides no teaching or guidance which correlates the sequence of SEQ ID NO:1 to its function, which amino acids in the protein encoded by SEQ ID NO: 1 are critical to its function, or how to modify SEQ ID NO: 1 to obtain any specific homolog, mutant, or variant. It is not clear which positions with SEQ ID NO: 1 can be substituted or altered without resulting in a loss of the function of SEQ ID NO: 1. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule is functionally equivalent to SEQ ID NO: 1. The claims provide for a large genus of nucleic acids that include undisclosed genes, partial genomic sequences, mutants, variants, and homologs of SEQ ID NO: 1, however the single disclosed structural feature of SEQ ID NO: 1 does not provide for a substantial potion of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of a substantially purified nucleic acid molecule consisting of the sequence of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of

the encompassed polynucleotides. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or isolating it. The polynucleotide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Accordingly, the specification does not provide a written description of the invention of claim 13-15.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

David R. Gunter, DVM, PhD
January 22, 2003

W. Gary Jones
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